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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,194	06/26/2003	Daniel J. Potter	11533US.00	7602
33486	7590	11/04/2005	EXAMINER	AHMED, AAMER S
HEIMBECHER & ASSOCIATES, LLC. 390 UNION BLVD SUITE 650 LAKEWOOD, CO 80228-6512			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/609,194	POTTER, DANIEL J.
	<b>Examiner</b>	<b>Art Unit</b>
	Aamer S. Ahmed	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 June 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 13-20 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 June 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/1903, 3/10/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to tearable hemostasis valve, classified in class 604 subclass 256.
- II. Claims 13-15, drawn to a method for removing a sheath, classified in class 29, subclass 867.
- III. Claims 16-20, drawn to a splittable sheath, classified in class 604, subclass 171.

The inventions are distinct, each from the other because of the following reasons:

Inventions tearable hemostasis device and method for removing a sheath are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the tearable hemostasis device as claimed can be used to practice another materially different process namely to limit blood flow during insertion of a pacemaker.

Inventions tearable hemostasis device and splittable sheath are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the

combination as claimed does not require the particulars of the subcombination as claimed because the tearable hemostasis device may be used without the splittable sheath. The subcombination has separate utility such as in a unitary catheter system.

Inventions splittable sheath and method for removing a sheath are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practice by another materially different apparatus, such as an electrical cord wire.

During a telephone conversation with Reed R. Heimbecher on June 7, 2005 a provisional election was made without traverse to prosecute the invention of Group I: A tearable hemostasis device, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### *Drawings*

The drawings are objected to because element 120 described in the specification regarding Figure 1 is not shown in Figure 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is

being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lui et al U.S. Publication Number 2001/0049499 A1. Lui describes a tearable hemostasis valve comprising a valve body 50, a first grip tab attached to the valve body at a first point, a second grip tab 32 attached to the valve body at a second point, a score line 55 on the valve body between the first and second points, a first membrane 112 disposed within the valve body bonded to and integral to the valve body and a snap-fit arrangement

attached to the valve body. (See Figure 9). Moreover, Lui discloses that the membrane 112 comprises a material of a first durometer (Paragraph 7) with a score 29 and the valve comprises a material of a second durometer (Paragraph 12) and the second durometer is higher than the first. Additionally Lui teaches that the valve further comprises a second membrane 28 disposed within the valve body, parallel to the first membrane and that two membrane are self-sealing. Furthermore, Lui describes that the snap-fit arrangement comprises a cavity in the valve 14 and an annular sidewall 20 defining an opening in communication with the cavity, such that the annular sidewall is flexible (Paragraph 7) and the opening 49 is located below the cavity and is located along one side of the cavity.

Thus Lui ('499) reasonably appears to teach and disclose every element of claims 1-12 and therefore anticipates these claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5330437	Durman
U.S. Pat. No. 5000745	Guest et al.
U.S. Pat. No. 6083207	Heck
U.S. Pat. No. 6623460	Heck
U.S. Pat. No. 6142981	Heck et al.
U.S. Pat. No. 5312355	Lee
U.S. Pub. No. 20030050604 A1	Lui et al.
U.S. Pat. No. 6712791	Lui et al.

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U.S. Pat. No. 5514098	Pfoslgraf et al.
U.S. Pat. No. 5643227	Stevens
U.S. Pat. No. 5755693	Walker et al.
U.S. Pat. No. 5397311	Walker et al.
U.S. Pat. No. 4626245	Weinstein
U.S. Pub. No. 20040162531 A1	Wenchell
U.S. Pat. No. 4743265	Whitehouse et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NICHOLAS D. LUCCESI  
SUPPLYING PATENT EXAMINER  
TECHNOLOGY CENTER 3700

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